DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region

95147d

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973)
526-6010

December 14, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Raymond Walsh
President/Owner
Gourmet Kitchen, Inc.
1238 Corlies Avenue (SR33 East)
Neptune, New Jersey 07753

05-NWJ-06

Dear Mr. Walsh:

We inspected your firm, located at 1238 Corlies Avenue, Neptune NJ, from August 13 through August 23, 2004, and found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 and the Current Good Manufacturing Practice (cGMP) for foods regulation, 21 CFR Part 110. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, as outlined below, your seafood hors d'oeuvres are adulterated in that they have been prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

These same or similar deviations and the need for their correction were brought to your attention during previous inspections in April 2001, September 2002, June 2003, and March 2004, and in untitled letters issued to your firm in 1998 and 1999.

1) You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's single HACCP plan for your hors d'oeuvres does not list the critical control point of storage of raw materials in walk-in and reach-in coolers. Our investigators observed that there was no temperature monitoring

of the reach-in cooler. During the inspection, the digital read out was observed to be incorrect, in that the read-out showed 39°F; however when the temperature was taken manually, the actual temperature of the reach-in cooler was 58°F. This is not adequate to control food safety hazards such as pathogen growth and toxin formation. In addition, there was no continuous monitoring system in place for the walk-in cooler. Temperatures were taken only [illegible] times per day and not at all on weekends; this is not adequate to control food safety hazards in the event of an unexpected temperature deviation/fluctuation that could easily go undetected.

2) You must implement the monitoring procedures that you have listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring frequency of taking temperatures of raw materials for each delivery of those materials at the receiving critical control point to control the hazard of bacterial pathogens as identified in your single HACCP plan for all hors d'oeuvres manufactured at your facility. Specifically, no receiving temperatures were recorded on receiving records for canned pasteurized crabmeat, liquid eggs, half & half, goat cheese, and cream cheese on numerous occasions from May through July 2004. Where there is a potential for pathogen growth and toxin formation, FDA recommends continuous monitoring of temperature during transit to control these hazards if the transit time of sensitive commodities is greater than 4 hours.

   In addition, your HACCP plan lists that you will monitor, "When Bags are removed from freezer, bag are immediately cut and placed into cooler." However your firm neither monitored nor recorded the slitting of the bags to prevent the formation of *Clostridium botulinum* toxin as required by your HACCP plan. You may wish to consider alternatives to slitting the bags for the control of *Costridium botulinum*. FDA considers the continuous monitoring of temperature during thawing as an effective alternative to breaking the vacuum in the bags.

3) Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for frozen vacuum packaged salmon, sea legs and tuna, "Hold and evaluate product based on total exposure to abusive temperature" does not describe how you will keep adulterated product from being introduced into commerce.

Several other seafood HACCP deficiencies and general Current Good Manufacturing Practice deficiencies were observed during the inspection and noted on the form FDA-483, List of Inspectional Observations, which was issued to your firm at the close of the inspection. In addition to the items listed above, you should take prompt action to correct all of the items listed on the FDA-483.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Current Good Manufacturing Practice regulation. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 working days of your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as revised HACCP plans, revised monitoring procedures, or other useful information that would assist us in evaluating your corrections. If you cannot complete the corrections before you respond, we expect that you will explain the reason for your delay and provide a deadline by which the remaining corrections will be completed.

You may send your response to: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director

cc: Ms. Patricia Duffy
Vice President, Co-Owner

Mr. Ryan Walsh
HACCP Coordinator

Enclosure: Form FDA-483, List of Inspectional Observations, dated 8/23/04